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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

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EXAMINER
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COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/815,573	<b>Applicant(s)</b> DELUCA ET AL.	
	<b>Examiner</b> Abigail M. Cotton	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This office action is in response to the amendment submitted April 25, 2006.

Claims 8-14 are pending in the application and are being examined herein.

Applicant's arguments filed April 25, 2006 have been fully considered but they are not persuasive. The claims remain rejected as follows.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al. (WO 96/24258) in view of U.S. Patent No. 5,145,695 to Smith et al, issued September 8, 1992.

Deluca et al. discloses a method of improving utilization of phosphorous such as to reduce or perhaps eliminate dietary requirement of phosphorous in animals (see abstract, page 3, lines 13-15, in particular) including in commercially significant

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mammals such as cattle (see page 10, lines 5-20, in particular.) Deluca et al. teaches the method involves feeding animals with the instantly claimed  $1\alpha$ -hydroxylated vitamin D compounds (see pages 7-8, in particular) in the effective amounts, about 5-40  $\mu\text{g/kg}$ , which is within the instantly claimed range (see page 10, lines 20-22 and claim 12, in particular.) Deluca et al. also teaches that the composition may be in the form of a top dressing (see page 9, line 3, in particular.) See also abstract, page 5 line 30 to page 6, line 3, page 9 lines 15-17 and claims 18-20, in particular.

DeLuca et al. does not expressly disclose the method herein comprising replacing all inorganic phosphorus in a diet with the known effective amount of a  $1\alpha$ -hydroxylated vitamin D of prior art. DeLuca et al. also do not expressly disclose that said feed contains 0% by weight of an inorganic phosphorous supplement.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to replace all inorganic phosphorus in a diet with the known effective amount of  $1\alpha$ -hydroxylated vitamin D of the prior art, and to provide said feed containing 0% by weight of an inorganic phosphorous supplement.

One having ordinary skill in the art at the time the invention was made would have been motivated to replace all inorganic phosphorous in a diet with the known effective amount of  $1\alpha$ -hydroxylated vitamin D of the prior art, and to provide said feed containing 0% by weight of an inorganic phosphorous supplement, since the known

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method of improving utilization of phosphorous that is capable of reducing or minimizing or perhaps eliminating dietary requirements of phosphorous in animals such as cattle, and comprising feeding with the same effective amount of the 1 $\alpha$ -hydroxylated vitamin D, about 5-40  $\mu$ g/kg, has been disclosed by DeLuca et al.

Thus, DeLuca et al. is seen to clearly provide the motivation for the instant method of eliminating the dietary requirement of phosphorous or replacing all inorganic phosphorous in a diet, by administering the same effective amount of the same vitamin D compound to cattle.

DeLuca et al. have furthermore provided the motivation for elimination or replacing all inorganic phosphorous in a diet for the sake of eliminating or reducing pollution by the phosphorous, by teaching that "low phosphorus containing animal feeds reduce the pollution effects on the environment since less phosphorous is excreted in the animal's feces which are then spread on agricultural land."

DeLuca et al. does not specifically teach performing the method with cattle that are dairy cows, as recited in the claims.

However, Smith et al. teaches that dairy cows are commercially significant, particularly for the production of milk in the dairy industry (see column 1, lines 5-40, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was

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made would have found it obvious to perform the method of DeLuca et al. on the specific type of cattle, dairy cows, of Smith et al, because DeLuca et al. teaches that the method is suitable for commercially significant mammals including cattle, and Smith et al. teaches that dairy cows are commercially significant cattle. Thus, one of ordinary skill in the art would have been motivated to perform the method of DeLuca et al. on the dairy cows of Smith et al. with the expectation of achieving the reduced pollution and low phosphorous benefits.

Thus, the claimed invention as a whole is clearly prima facie obvious over the cited prior art.

### ***Response to Arguments***

Applicant's arguments filed April 25, 2006 have been fully considered but they are not persuasive.

In particular, Applicants assert that the state of the prior art at the time of filing was such that it was believed that phosphorous was not adequately supplied by most feedstuffs and as a result, it was believed that phosphorous must be supplemented in some manner. Applicants cite articles by the Kansas State University, the University of Florida and the Midwest Plan Service showing that it is standard practice in the art to supplement dairy cow feed with phosphorous to provide the proper nutritional content. Applicants thus assert that, based on these teachings of the necessity of providing

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supplemental phosphorous, one of ordinary skill in the art would not find it "reasonable" to eliminate all supplemental inorganic phosphorous from the diet of a milk producing dairy cow, as required by the instant claims, and thus the state of the prior art at the time of the invention teaches away from the invention as claimed.

The Examiner agrees that the cited references teach the desirability of providing supplemental phosphorous. However, the Examiner also notes that the WO 96/24258 reference to DeLuca et al. teaches that, while it is known to provide supplemental phosphorous in feed, it is possible to minimize and even eliminate the supplemental phosphorous provided by feeding the vitamin D compounds as instantly claimed (see abstract, in particular.) DeLuca et al. clearly teaches that the prior art Vitamin D compounds increase the biological utilization of phosphorous from the non-inorganic source phytate, and thus can allow for a lower amount of phosphorous supplements (a low phosphorous diet) and can perhaps even allow for the elimination of inorganic phosphorous supplements in the diet (see page 3, lines 1-15, in particular.) Accordingly, one of ordinary skill in the art would reasonably expect to achieve this improved utilization of phosphorus in mammals such as cattle as taught by DeLuca et al., and including in lactating cattle, and thus would reasonably expect that a reduced phosphorous supplement diet could be provided in such lactating cattle due to the improved phosphorous utilization brought about by administration of the vitamin D compounds.

Applicants further argue that there is nothing in the cited prior art that teaches that milk production in dairy cows could be maintained despite having had all the supplemental phosphorous removed from their diets. The Examiner notes that De Luca et al. also teaches that phosphorous is obtained in animal diets through ingestion of plant food such as phytate (see page 1, lines 5-30, in particular), and teaches that the utilization of such phytate can be improved with the vitamin D compounds, such that extra inorganic phosphate supplements can be reduced and even eliminated from the diet (see page 3, lines 1-30, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would understand that the necessary dietary phosphorous, as indicated by the documents cited by Applicants, could still be achieved via ingestion of phytate or other plant-based feeds in the method of DeLuca et al, with the utilization of such phytate being enhanced by the vitamin D compounds such that little or even no phosphorous supplement is required.

Applicants furthermore argue that DeLuca et al's teaching that the animal feed can "perhaps" eliminate the need for supplemental phosphorus (see abstract, in particular) is not an affirmative teaching to eliminate or replace all inorganic phosphorous in the diet. The examiner recognizes that obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*



*Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, DeLuca et al. teaches that the vitamin D compound enhances the utilization of sources of phosphorus such as phytate found in food-stuffs such that the amount of supplemental phosphorus required is at least reduced, and may even be eliminated, and that such phosphorous reduction and/or elimination reduces pollution. Accordingly, DeLuca et al. clearly provides motivation to provide the instant vitamin D compound with a low phosphorous diet, and even without any inorganic phosphorous supplements, with the expectation of the likelihood of achieving sufficient phosphorous intake from non-supplemental sources such as phytate, and with the expectation of reducing phosphorous pollution.

Applicant's also argue that the invention is not obvious over the references because they constitute merely an "invitation to explore", but do not otherwise provide an enabling disclosure of the claimed method. The Examiner notes that the question of enablement of a reference hinges on whether one of ordinary skill in the art would be required to carry out undue experimentation in order to perform a method as taught in the reference. The Examiner considers that it would not require undue experimentation to carry out the method of supplement replacement as in DeLuca et al, because DeLuca et al. teaches the vitamin D compounds suitable for phosphorous supplementation replacement, and teaches general amounts of the compound per weight of animal that may be provided to reduce the amount of phosphorous needed (see page 10, lines 18-30, in particular.) Thus, it is considered that one of ordinary skill in the art would be able to carry out the method of the instant claims, based on the teachings of DeLuca et al,

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for example by completely removing supplemental phosphorous from the diet and providing amounts of the vitamin D compound believed to be suitable to replace with supplemental phosphorous, without requiring anything more than merely routine experimentation. Accordingly, it is considered that the DeLuca reference enables one of ordinary skill in the art to replace phosphorous with the vitamin D compound as claimed.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER